

## REMARKS

Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested.

Claims 17 - 38 are pending in this application. Claims 6-9 and 11-15 have been withdrawn from consideration; and claims 17-38 stand rejected.

Claims 17, 21, 25, and 29 have been amended to clarify that the claimed antibodies are “Insulin Receptor Substrate-1/2 specific”. Support for these amendments can be found throughout the Application (see, for example, page 13, lines 16-20).

Claim 38 has been amended to remove the amendment made by Applicants in their May 2, 2008 response. Support for amendment can be found throughout the Application (see, for example, page 30, line 18 to page 31, line 12).

Applicants aver that none of the claim amendments introduces new subject matter as support may be found throughout the specification of the Application and respectfully request entry of the claims as amended.

The specification has also been amended to correct inadvertent typographical errors. Further, insofar as these amendments to the specification may be considered new matter, Applicants respectfully note that the Federal Circuit stated in In Re Paul Lew and Jason Schiers (2007-1196) that:

The claimed subject matter need not be described “in haec verba” in the original specification in order to satisfy the written description requirement. *In re Wright*, 866 F.2d at 425. Rather, “the test . . . is whether a person of ordinary skill in the art would recognize that the applicant possessed what is claimed in the later filed application as of the filing date of the earlier filed application.” *Noelle v. Lederman*, 355 F.3d 1343, 1348 (Fed. Cir. 2004). The same standards govern whether new matter has been added to the specification. See *TurboCare*, 264 F.3d at 1118.

Applicants respectfully aver that the invention, as stated in the Summary of the Invention at page 6, lines 10-15, “discloses a novel human IRS-1 phosphorylation site, serine 1101 (Ser1101), and a homologous novel phosphorylation site, serine 1149 (Ser1149) in human IRS-2, as well as homologous sites in mouse IRS-1 (Ser1095) and IRS-2 (Ser1138), and provides

antibodies that selectively bind to IRS-1 and/or IRS-2 when phosphorylated at these novel sites.” Applicants respectfully aver that the assays and the kits of the invention, as described, for example, at page 26, line 1 through page 31, line 12, include human and mouse IRS-1 and IRS-2 phosphorylation sites, and antibodies that selectively bind such phosphorylated human and mouse IRS-1 and IRS-2 molecules.

Accordingly, Applicants aver that none of the amendments to the specification introduces new subject matter as support may be found throughout the specification of the Application and respectfully request entry of the specification as amended.

Each of the rejections set forth in the Office Action are addressed separately below.

**I. 35 USC § 102(b) Rejections:**

**a. Rejection of Claims 17-33 under 35 USC § 102(b) over U.S Patent No:**

**5,593,678 (hereinafter “the ‘678 patent”)**

Claims 17 – 33 stand rejected under 35 USC § 102(b) as being anticipated by U.S Patent No: 5,593,678 (hereinafter “the ‘678 patent”).

Applicants have responded this ground for rejection with the present amendments to the claims and the following remarks.

As an initial matter, Applicants respectfully clarify an inference made in the Office Action, page 2, paragraph 5, final sentence. The sentence “The fact that the antibody binds all phosphorylated serines...” is incorrect—Applicants respectfully note that the claimed Insulin Receptor Substrate-1/2 phospho-specific antibodies do not necessarily bind all phosphorylated serines. Rather, while some claimed antibodies indeed bind more than one phosphorylated serine, the claims also cover an Insulin Receptor Substrate-1/2 phospho-specific antibody that either binds to human Insulin Receptor Substrate-1 (IRS-1) when phosphorylated at serine 1101 (SEQ ID NO: 1), but does not bind human IRS-1 when not phosphorylated at serine 1101 (claim 17); binds to human IRS-2 when phosphorylated at serine 1149 (SEQ ID NO: 2), but does not bind human IRS-2 when not phosphorylated at serine 1149 (claim 21); binds to murine IRS-1 when phosphorylated at serine 1095 (SEQ ID NO: 3), but does not bind murine IRS-1 when not phosphorylated at serine 1095 (claim 25); or binds to murine IRS-2 when phosphorylated at

serine 1138 (SEQ ID NO: 4), but does not bind murine IRS-2 when not phosphorylated at serine 1138 (claim 29).

Turning to the '678 patent, Applicants respectfully aver that the present amendments to the claims have overcome the grounds for this 35 USC § 102(b) rejection. The '678 patent fails to teach or suggest SEQ ID NOs: 1-4 nor does it teach or suggest insulin receptor substrates 1/2. Having failed to teach or suggest insulin receptor substrates 1/2, the '678 patent also fails to teach or suggest an IRS-1/2 phospho-specific antibody as now required by the present claims.

Based on these remarks, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

**b. Rejection of Claims 17-32 and 34 under 35 USC § 102(b) over U.S Patent No: 5,807,702 (hereinafter “the ‘702 patent”)**

Claims 17 – 32 and 34 stand rejected under 35 USC § 102(b) as being anticipated by U.S Patent No: 5,807,702.

Applicants have overcome this ground for rejection by the present amendments to the claims. The '702 patent fails to teach or suggest SEQ ID NOs: 1-4 nor does it teach or suggest insulin receptor substrates 1/2. Similarly, having failed to teach or suggest insulin receptor substrates 1/2, the '702 patent fails to teach or suggest an IRS-1/2 phospho-specific antibody as now required by the present claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

**c. Rejection of Claims 17-32, 34, and 35 under 35 USC § 102(b) over Product P3430 of the Sigma Catalog 1998 (hereinafter “the Sigma Catalog”)**

Claims 17 – 32, 34, and 35 have been rejected under 35 USC § 102(b) as being anticipated by The Sigma Catalog.

Applicants have overcome this ground for rejection by the present amendments to the claims. The Sigma Catalog fails to teach or suggest SEQ ID NOs: 1-4, nor does it teach or suggest insulin receptor substrates 1/2. Having failed to teach or suggest insulin receptor substrates 1/2, the Sigma Catalog fails to teach or suggest an IRS-1/2 phospho-specific antibody as now required by the present claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

## **II. 35 USC § 103(a) Rejection:**

Claims 36 - 38 stand rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,593,678 or U.S. Patent No. 5,807,702 in view of U.S. Patent No. 4,208,479 (hereinafter “the ‘479 patent”).

Applicants’ amendments to claims 17, 21, 25, and 29 (which amendments are incorporated into claims 36-38) have rendered moot this ground for rejection.

Neither the ‘678 patent, the ‘702 patent, nor the ‘479 patent teaches or suggests an IRS-1/2 phospho-specific antibody, as required by the present claims. As none of the cited references teaches or suggests an element required by the claims, their combination cannot render the claimed antibodies obvious to the ordinarily skilled artisan.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

## **III. 35 USC § 112, first paragraph, Rejections:**

### **a. Enablement of Claim 38**

Claim 38 stands rejected under 35 USC § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have overcome this ground for rejection with the present amendment to claim 38, and the present amendments to claims 17, 21, 25, and 29, which amendments are incorporated into claim 38.

As described by Applicants in their May 2, 2008 communication, paragraphs [0040 - 0045 and 0063 – 0069] (including the references cited therein), Examples 1 & 2, and Figs. 11, 12, & 14 provide written support and describe the procedures for detecting PKC theta activity in

full compliance with the requirements of 35 USC § 112, first paragraph. Applicants respectfully aver that the ordinarily skilled artisan, upon reading the specification and without undue experimentation, would be able to make and/or use presently claimed kit.

Based on these remarks and amendments, Applicants respectfully request reconsideration and withdrawal of this 35 USC § 112, first paragraph rejection of Claim 38.

**b. Written Description of Claim 38**

Claim 38 additionally stands rejected under 35 USC § 112, first paragraph for failing to comply with the written description requirement. Specifically, the Office Action avers that the specification supports only kits comprising the antibodies of claims 17 and 21.

Applicants respectfully traverse this ground for rejection.

Applicants respectfully aver that the Office Action's assertion that the specification supports only kits comprising the antibodies of claims 17 and 21 is based on an inadvertent typographical error using the word "i.e." instead of "e.g." at page 31, line 6). Applicants regret this typographical error and have amended the specification to correct this error.

Applicants respectfully submit that the presently amended specification provides adequate written description support for kits comprising the antibodies of claims 17, 21, 25, or 29. Accordingly, Applicants respectfully request reconsideration and withdrawal for this ground for rejection.

**CONCLUSIONS**

On the basis of the preceding amendments and remarks, this Application is believed to be in condition for allowance. Accordingly, reconsideration of the claims as amended and their allowance are kindly requested.

A request for a One (1) Month Extension of Time, up to and including December 8, 2008 (December 7 being a Sunday), pursuant to 37 C.F.R. §1.136 is hereby requested. The Examiner is authorized to charge any fees applicable in the instant, as well as in future communications, to Deposit Account No. 50-1774, Ref No: CST-209. Such an authorization should be treated as a constructive petition for extension of time in the concurrent as well as future replies.

The Examiner is encouraged to call the undersigned to facilitate prosecution.

Respectfully submitted,  
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